gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) *Sponsor*. See No. 051079 in §510.600(c) of this chapter.

(b)(1) *Specifications*. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) *Sponsor*. See No. 017135 in §510.600(c) of this chapter.

(c) *Conditions of use*. The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 56307, Dec. 28, 1976; 50 FR 9800, Mar. 12, 1985; 54 FR 25565, June 16, 1989; 56 FR 37474, Aug. 7, 1991; 66 FR 46369, Sept. 5, 2001; 72 FR 36595, July 5, 2007]

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

526.88 Amoxicillin trihydrate for intramammary infusion.
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526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).
526.1696d Penicillin G procaine-novobiocin for intramammary infusion.
526.1810 Pirlimycin.

AUTHORITY: 21 U.S.C. 360b.

§526.88 Amoxicillin trihydrate for intramammary infusion.

(a) *Specifications*. Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000061 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.38 of this chapter.

(d) *Conditions of use—Lactating cows*—(1) *Amount*. One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

(2) *Indications for use*. For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Straphylococcus aureus* (penicillin sensitive).

(3) *Limitations*. Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§526.313 Ceftiofur.

(a) *Specifications*. Each single-use, 10-milliliter syringe of ceftiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use in cattle*—(1) *Lactating cows*—(i) *Amount*. Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use*. For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.

(iii) *Limitations.* Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day pre-slaughter withdrawal period is required.

(2) *Dry cows*—(i) *Amount.* Infuse 500 mg per affected quarter at the time of dry off.

(ii) *Indications for use.* For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations.* Milk taken from cows completing a 30-day dry off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day pre-slaughter withdrawal period is required for treated cows. Following label use, no preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005. Redesignated and amended at 71 FR 39545, July 13, 2006]

§ 526.363 Cephapirin benzathine.

(a) *Specifications.* Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Infuse the contents of one syringe into each quarter.

(2) *Indications for use.* Use in dry cows for treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*, including penicillin-resistant strains.

(3) *Limitations.* Infuse each quarter following last milking, but no later than 30 days before calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. For use in dry cows only.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988; 73 FR 12262, Mar. 7, 2008; 75 FR 10168, Mar. 5, 2010; 76 FR 17338, Mar. 29, 2011]

§ 526.365 Cephapirin sodium.

(a) *Specifications.* Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanut-oil gel.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse one dose into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

(2) *Indications for use.* For the treatment of mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus* including strains resistant to penicillin.

(3) *Limitations.* If improvement is not noted within 48 hours after treatment, consult your veterinarian. Milk that has been taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988. Redesignated at 63 FR 8349, Feb. 19, 1998; 65 FR 20733, Apr. 18, 2000; 73 FR 3181, Jan. 17, 2008; 75 FR 10168, Mar. 5, 2010]

§ 526.464 Cloxacillin intramammary dosage forms.

§ 526.464a Cloxacillin benzathine.

(a) *Specifications.* Each dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer aseptically into each quarter immediately after last milking.

(2) *Indications for use.* For the treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Animals infused with this product must not be slaughtered for food use for 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer one dose in each quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in nonlactating cows due to *S. agalactiae* and *S. aureus.*

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 75 FR 10168, Mar. 5, 2010; 75 FR 71017, Nov. 22, 2010]

§ 526.464b Cloxacillin benzathine for intramammary infusion, sterile.

(a) *Specifications.* Each 6 milliliter dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(1) *Amount.* 6 milliliters per infected quarter aseptically immediately after last milking at the time of drying-off of the cow.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococus agalactiae* in dairy cows at the time of drying-off of the cow.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for human food. Animals infused with this product must not be slaughtered for food from the time of infusion until 72 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(1) *Amount.* One dose per infected quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in nonlactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus.*

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.464c Cloxacillin sodium for intramammary infusion, sterile.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent to 20.0 milligrams of cloxacillin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use. Lactating cows—*(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus,* nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (four milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law

restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.464d Cloxacillin sodium for intramammary infusion.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent 20.0 milligrams of cloxacillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions for use. Lactating cows*—(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

§ 526.820 Erythromycin.

(a) *Specifications.* (1) Each 6-milliliter, single-dose, disposable syringe contains 300 milligrams of erythromycin (as the base), 0.45 milligram of butylated hydroxyanisole, and 0.45 milligram of butylated hydroxytoluene.

(2) Each 12-milliliter, single-dose, disposable syringe contains 600 milligrams of erythromycin (as the base), 0.90 milligram of butylated hydroxyanisole, and 0.90 milligram of butylated hydroxytoluene.

(3) The vehicle is triglyceride of saturated fatty acids from coconut oil.

(4) The drug may or may not be sterile.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) Lactating cows: After milking, cleaning, and disinfecting, infuse contents of a single 6-milliliter syringe into each infected quarter; repeat procedure at 12-hour intervals for a maximum of 3 consecutive infusions.

(ii) Dry cows: After milking, cleaning, and disinfecting, infuse contents of a single 12-milliliter syringe into each infected quarter at the time of drying off.

(2) *Indications for use.* Treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating or dry cows.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

[47 FR 15772, Apr. 13, 1982, as amended at 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 526.1130 Hetacillin potassium for intramammary infusion.

(a) *Specifications.* Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use. Lactating cows*—(1) *Amount.* 10 milliliters of hetacillin potassium equivalent to 62.5 milligrams ampicillin into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

(2) *Indications for use.* Treating acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus*, and *Escherichia coli*.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 75 FR 10168, Mar. 5, 2010]

§ 526.1590 Novobiocin oil suspension.

(a)(1) *Specifications.* Each 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount.* Ten milliliters (equivalent to 400 milligrams of novobiocin) infused in each quarter.

(ii) *Indications for use.* It is used in dry cows for the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae.*

(iii) *Limitations.* Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food use for 30 days following udder infusion. For udder installation for the treatment of mastitis in dry cows only.

(b)(1) *Specifications.* Each 10 milliliters of oil suspension contains the equivalent of 150 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount.* Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.

(ii) *Indications for use.* Use in lactating cows for treatment of mastitis caused by susceptible strains of *Staphylococcus aureus.*

(iii) *Limitations.* Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 10554, Mar. 14, 1978]

§ 526.1696 Penicillin intramammary dosage forms.

§ 526.1696a Penicillin G procaine.

(a) *Specifications.* Each 10-milliliter single-dose syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) *Related tolerances.* See § 556.510 of this chapter.

(c) *Sponsors.* See Nos. 010515 and 061623 in § 510.600(c) of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae, S. dysgalactiae,* and *S. uberus* in lactating cows.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) *Conditions of use in dry cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter at time of drying-off.

(2) *Indications of use.* For the treatment of mastitis caused by *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[73 FR 18442, Apr. 4, 2008, as amended at 74 FR 18990, Apr. 27, 2009]

§ 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows*—(1) *Amount.* One syringe into each quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae.*

(3) *Limitations.* Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992]

§ 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.

(b) *Sponsor.* See No. 033392 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows*—(1) *Amount.* One syringe per quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations.* Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) *Specifications.* For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Lactating cows*—(i) *Amount.* 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use.* Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis.*

(iii) *Limitations.* For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount.* 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use.* Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae.*

(iii) *Limitations.* For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

§528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use*. Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor*. See No. 042976 in §510.600 of this chapter.

(c) *Limitations*. Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.
529.56 Amikacin.
529.400 Chlorhexidine tablets and suspension.
529.536 Detomidine.
529.1030 Formalin.
529.1044 Gentamicin sulfate in certain other dosage forms.
529.1044a Gentamicin sulfate intrauterine solution.
529.1044b Gentamicin sulfate solution.
529.1115 Halothane.
529.1150 Hydrogen peroxide.
529.1186 Isoflurane.
529.1350 Meloxicam.
529.1660 Oxytetracycline.
529.1940 Progesterone intravaginal inserts.
529.2150 Sevoflurane.
529.2464 Ticarcillin powder.
529.2503 Tricaine methanesulfonate.
529.2620 Triptorelin.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§529.40 Albuterol.

(a) *Specifications*. A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals*. See No. 000010 in §510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.